A1

1. (Amended) A solvated form of crystalline lamotrigine containing a solvate, wherein the solvate is selected from the group consisting of dimethylformamide, dimethylamine, tetrahydrofuran, methyl-isobutyl-ketone, methyl-tertiary-butyl-ether, water and acetone.

A2

92. (Amended) A pharmaceutical composition comprising a therapeutically effective amount of at least one lamotrigine form selected from the group consisting of lamotrigine forms B, C, D, F, K, L, M, N, P, R, S and U; and, a pharmaceutically acceptable excipient.

93. (Amended) A method for treating a patient suffering from epilepsia by administering a therapeutically effective amount of at least one lamotrigine form selected from the group consisting of lamotrigine forms B, C, D, F, K, L, M, N, P, R, S, and U.

Please add the following new claims:

117. (New) A method for preparing lamotrigine form A, comprising the step of heating a lamotrigine solvate at an elevated temperature sufficient to remove solvent from the lamotrigine solvate.

118. (New) The method of claim 117, wherein the lamotrigine solvate is selected from the group consisting of lamotrigine forms B, C, D, F, K, L, M, N, P, R, S, and U.

A3

119. (New) The method of claim 118, wherein the lamotrigine solvate is heated at about 110^0C for about 2 hours.

120. (New) The method of claim 118, wherein the lamotrigine solvate is heated at about 110^0C for about 1 hour.

121. (New) The method of claim 118, wherein the lamotrigine solvate is heated at about 150^0C for about ½ hour.

122. (New) The method of claim 120, wherein the lamotrigine solvate is lamotrigine form L.

123. (New) The method of claim 120, wherein the lamotrigine solvate is lamotrigine form N.

STATUS OF THE CLAIMS:

Claims 17-25, 32-41, 62-66, and 72-76 have been canceled without prejudice. New claims 117-123 have been added. Support for the added claims can be found in the specification (e.g., page 4, lines 6-11) and examples 1 and 2 (page 23). No new matters are introduced. The pending claims are 1-16, 26-31, 42-61 and 77-123.

All claims 1-116 stand rejected under 35 U.S.C.§ 102. Claim 1 stands rejected under 35 U.S.C.§ 112, 2nd paragraph. Claims 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, et seq., stand

rejected under 35 U.S.C.§ 112, 2nd paragraph. Claims 2, 7, 12, 17, 22, 27, 32, 37, 42, 47, 52, 57, et seq., stand rejected under 35 U.S.C.§ 112, 2nd paragraph. Claims 6, 11, 16, 21, 26, 36, 41, et seq., stand rejected under 35 U.S.C.§ 112, 2nd paragraph. Claim 92 stands rejected under 35 U.S.C.§ 112 as unclear. Claims 92 and 93 stand rejected under 35 U.S.C. § 103.

REMARKS

Applicants' Invention

Applicants' invention is directed to crystalline lamotrigine forms, designated as forms B, C, D, E, E1, F, H, J, K, L, M, N, O, P, Q, R, S, and U and pharmaceutical composition thereof. Each of these crystalline lamotrigine forms may be characterized by unique XRD spectra and/or thermogravimetric data. Applicants' invention also relates to the methods for preparing these crystalline lamotrigine forms and form A.

It appears that the Examiner has not fully understood the applicants' invention. The Examiner's reliance on (iii) Purer Forms of Old Products [See Section IIDI(c)(I)] from "Chemical Patent Practice" by John L. White (1988 Edition) which is directed to "Purer Forms of Old Products" is not fully understood. The claimed invention is directed to new crystalline form of lamotrigine, not specifically purer forms of lamotrigine. The new crystalline forms of lamotrigine represent a difference in solid-state chemistry.

Applicants respectfully direct the Examiner's attention to (v) "Unobvious Novel Physical Forms" [See Section IID1(c)(iii)] in the "Chemical Patent Practice" by John L. White (1993 Edition), which discusses patentability of a new physical form (i.e., crystalline form). It states:

> "However, old chemical products in a novel physical form have been held patentable. In re Berry (CCPA 1963) 315 F2d 916, 137 USPQ 353. This is true even where the only advantage is an improvement in the same utility. Ex parte Conn et al. (POBA 1955) 119 USPQ 388 (a crystalline synthetic penicillin in platelets of specific length to width ratio); Ex parte Welch (POBA) 1939) 44 USPQ 318, (nickel electrode of a specified grain size and count)...
>
> The crystalline form of a compound which heretofore existed as a glassy amorphous solid is patentable, even though its existence in such form could be predicted, if it was not obvious how such a product could be produced. In re Irani et al. (CCPA 1970) 427 F2d 806, 166 USPQ 24."
> (p.171, line 9- p. 172, line 14)

MPEP § 2144.04 Section VII cites the In re Cofer case which is pertinent to patentability of a new crystalline form: